



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,629	07/05/2001	Shuang Liu	PH-7176	5136

24348 7590 12/12/2002

BRISTOL-MYERS SQUIBB PHARMA COMPANY
PATENT DEPARTMENT
P.O. BOX 4000
PRINCETON, NJ 08543-4000

EXAMINER

SHARAREH, SHAHNAM J

ART UNIT PAPER NUMBER

1617

DATE MAILED: 12/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/899,629

Applicant(s)

LIU ET AL.

Examiner

Shahnam Sharareh

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-92 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-92 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-18, 59-64, 77, drawn to radiolabeled pharmaceutical agents with a metal chelator and a peptidomimetic, classified in class 424, subclass 1.41.
- II. Claims 1-18, 59-64, 75-77, drawn to radiolabeled pharmaceutical agents without a metal chelator, but direct linkage and a non-peptide, classified in class 424, subclass 1.65.
- III. Claims 1-18, 59-64, 75-77, drawn to radiolabeled pharmaceutical agents with a metal chelator and a non-peptide, classified in class 534, subclass 10+.
- IV. Claims 1-18, 59-64, 75-77, drawn to radiolabeled pharmaceutical agents without a metal chelator, but direct linkage and a peptidomimetic, classified in class 424, subclass 1.69 or class 530, subclass 300.
- V. Claims 19-38, drawn to radiolabeled pharmaceutical agents with a metal chelator and a peptidomimetic, classified in class 424, subclass 1.41.
- VI. Claims 19-38 drawn to radiolabeled pharmaceutical agents without a metal chelator, but direct linkage and a non-peptide, classified in class 424, subclass 1.65.
- VII. Claims 19-38, drawn to radiolabeled pharmaceutical agents with a metal chelator and a non-peptide, classified in class 534, subclass 10+.

- VIII. Claims 19-39, drawn to radiolabeled pharmaceutical agents without a metal chelator, but direct linkage and a peptidomimetic, classified in class 424, subclass 1.69.
- IX. Claims 40-45, 78 drawn to methods of preparing a radiolabeled composition, classified in class 424, and subclass 1.11.
- X. Claims 46-51, drawn to methods of use, classified in class 424, subclass 193.1+.
- XI. Claims 52-58, 65-76 drawn to methods for imaging a tumor, classified in class 424, subclass 9.1.
- XII. Claims 79-92, drawn to methods of treating cancer, classified in class 514, subclass 283+.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, III, IV and V, VI, VII, VIII are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because it can provide utility when the compound of formula (I) is (1) a substituted monohydroxyl aromatic compound, (2) a substituted dihydroxyl aromatic compound, (3) a substituted monohydroxyl-monohydroxyl-monoamino aromatic compound, or (4) an ortho, meta, or

Art Unit: 1617

para aminobenzioc acid. The subcombination has separate utility such as imaging or contrast agents.

Inventions I-VIII and X-XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process of using the product as claimed can be practiced with another materially different products such as those taught by Edwards et al in US Patent 5,879,659.

Inventions IX and I-VIII, X-XII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the products can be made by different process such as those described by Edwards et al in US Patent 5,879,659.

Inventions I,II,III,IV,V,VI,VII, and VIII are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, each invention has separate utility in the field of diagnostic or therapeutic medicine and can be employed individually or in combination with the other to provide the intended effects. See MPEP § 806.05(d).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the search required for each Group is not required for the other, restriction for examination purposes as indicated is proper.

Claims 1-92 are generic to a plurality of disclosed patentably distinct species comprising

- An RI
- Ch
- Ln
- BM
- A1-A6
- A second stabilizer as recited in claim 17
- A specific disease as recited in claims 46 or 50
- And a chemotherapeutic agent

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Accordingly, if any of the composition groups are elected, a species from the groups RI, Ch, Ln, BM, A1-A6 and stabilizer of choice is required to be selected. If a method group is elected then the specific type of disease and the chemotherapeutic agent of choice is required to be elected.

By species is meant a single compound. The compound may be named in any of four ways (or any combination thereof): (a) according to the IUPAC standard, (b) by a

Art Unit: 1617

pictorial representation of the compound, (c) by setting forth the specific chemical group that each variable of the Markush group represents, or (d) by naming a claim or an example which itself sets forth a single compound.

Since the instant claims are drawn to a composition of matter which contains more than one group of compounds, a single compound (as described above) should be elected for each group of compounds. It is not necessary to elect a single compound for groups of compounds which are inert and have no bearing on the patentability of the composition (e.g. it would not usually be necessary to elect which solvent or buffer system the composition will be associated with.)

Furthermore, applicant is informed that the recitation of the instant claims are drawn in Markush format, encompassing independent and patentably distinct compositions and methods of use. In the event that the Markush-type species are not found to be allowable, the examination of the claims presented will be limited to the Markush-type species to the extent that they read on the elected claim. The claims directed solely to the non-elected species will be held withdrawn from consideration. See MPEP § 803.02.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the

Art Unit: 1617

case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

A telephone call was made to Mr. Dolan on December 6, 2002 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Application/Control Number: 09/899,629

Page 8

Art Unit: 1617

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

SS

December 6, 2002


RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200